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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/068,591 | 02/06/2002 | Duojia Pan | B01-019-2 | 1004 |
| 23379 | 7590 | 01/22/2004 | EXAMINER | |
| RICHARD ARON OSMAN SCIENCE AND TECHNOLOGY LAW GROUP 75 DENISE DRIVE HILLSBOROUGH, CA 94010 | | | NICKOL, GARY B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|-----------------------------------|--|
| Office Action Summary | Application No. 10/068,591 | Applicant(s) PAN ET AL. | |
| | Examiner Gary B. Nickol Ph.D. | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Re: Pan *et al.*

Date of priority: 10/27/2000

Claims 1-17 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 5-6, drawn to a method for modulating angiogenesis in a vertebrate animal predetermined to have a pathogenic angiogenesis comprising contacting the animal with an agent which binds Kuz wherein said agent comprises a metalloprotease inhibitor, classified in class 514, subclass 2.
- II. Claims 1-4, 8, 12-13, drawn to a method for modulating angiogenesis in a vertebrate animal predetermined to have a pathogenic angiogenesis comprising contacting the animal with an agent which binds Kuz wherein said agent comprises a competitive inhibitor of a metalloprotease, classified in class 514, subclass 1.
- III. Claims 1, 7, drawn to a method for modulating angiogenesis in a vertebrate animal predetermined to have a pathogenic angiogenesis comprising contacting

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the animal with an agent which binds Kuz wherein said agent comprises a Kuz-specific antibody, classified in class 424, subclass 130.1.

- IV. Claims 1, 9-11, drawn to a method for modulating angiogenesis in a vertebrate animal predetermined to have a pathogenic angiogenesis comprising contacting the animal with an agent which specifically competes with Kuz for a substrate or cofactor wherein the agent comprises a dominant negative Kuz mutant, classified in class 424, subclass 185.1.
- V. Claims 14-15, drawn to a method for detecting Kuz activity in a vertebrate animal predetermined to have a pathogenic angiogenesis comprising use of a Kuz specific protease assay or a KUZ specific immunobinding assay, classified in class 424, subclass 9.2, and class 435 subclasses 4, 7.92.
- VI. Claims 16-17, drawn to a method for detecting angiogenesis comprising specifically detecting a pathogenic angiogenesis in a vertebrate animal having a predetermined Kuz activity wherein the detecting step comprises detecting a tumor, classified in class 436, subclass 64.

The inventions of Groups I-VI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for

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success. For example, the inventions of Groups I and VI differ in objectives, and method steps, and reagents. Also, the inventions of Groups I and III differ in method steps and reagents employed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

SPECIES ELECTION:

Group I (Claims 5-6) is generic to a plurality of disclosed patentably distinct species comprising the following metalloprotease inhibitors:

- a) TACE
- b) IC-3
- c) GM6001
- d) GW9471
- e) BB-94

Group II (Claims 4, 12) is generic to a plurality of disclosed patentably distinct species comprising the following competitive inhibitors:

- a) substituted hydroxamates

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- b) carboxylates
- c) thiols
- d) phosphonates
- e) aminodiathiazols
- f) catechols
- g) a chelator of divalent cations

In the event that the elected species above is a chelator of divalent cations, applicant must additionally elect from the following disclosed patentably distinct species of chelators in Claim 13:

- a) EDTA
- b) 1, 10-phenanthroline

Group V (Claim 15) is generic to a plurality of disclosed patentably distinct species comprising the following:

- a) KUZ specific protease assay
- b) KUZ specific immunobinding assay

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such,

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each species would require different searches and the consideration of different patentability issues.

Additionally, the steps and reagents of the above species are completely distinct and impart different biological functions and uses such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at 571-272-0871. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
January 20, 2004

